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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE D 08/944.850 10/06/97 WALT TU-97-01 **EXAMINER** MM42/0811 ROBIN M. SILVA, ET AL. HANNAHER, C FLEHR HOHBACH TEST ALBRITTON ART UNIT PAPER NUMBER & HERBERT, LLP 4 EMBARCADERO CENTER, SUITE 3400 2878 SAN FRANCISCO CA 94111-4187 DATE MAILED: 08/11/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

		Application No.	Applicant(s)		
Office Action (Summarı	08/944,850	Walt et	.,	
Office Action S	Sullillial y	Examiner Constantine Han		Group Art Unit 2878	
-The MAILING DATE of th	is communication app	ears on the cover sheet	beneath the c	correspondence address-	
Period for Reply					
A SHORTENED STATUTORY PER OF THIS COMMUNICATION.	IOD FOR REPLY IS SE	T TO EXPIRE THREE (3) MONTH(S	S) FROM THE MAILING DATE	
 Extensions of time may be available to from the mailing date of this communities. If the period for reply specified above. If NO period for reply is specified above. Failure to reply within the set or extension. 	cation. is less than thirty (30) days, ve. such period shall, by defa	a reply within the statutory min	imum of thirty (30 rom the mailing da	days will be considered timely. ate of this communication .	
Status					
✓ Responsive to communication	(s) filed on March 29	, 1999		•	
☐ This action is FINAL.					
 Since this application is in cor accordance with the practice to 	idition for allowance exc under <i>Ex parte Quayle,</i> 1	ept for formal matters, pro 1935 C.D. 1 1; 453 O.G. 2	osecution as to 13.	o the merits is closed in	
Disposition of Claims					
	1-17 and 24-38				
Of the above claim(s)	claim(s) 1-17 and 24-27			is/are withdrawn from consideration	
Claim(s)	28-38		is/are	is/are rejected.	
☐ Claim(s)			is/are	objected to.	
Claim(s)	1-17 and 24-3	8	are s	ubject to restriction or election	
Application Papers			. requi	rement.	
See the attached Notice of Dr					
☐ The proposed drawing correc				ed.	
☐ The drawing(s) filed on	is/are ob	pjected to by the Examiner	r.		
The specification is objected to	-				
☐ The oath or declaration is obj	ected to by the Examine	r.			
Priority under 35 U.S.C. § 119 (a)					
☐ Acknowledgment is made of a☐ All ☐ Some* ☐ None of a☐ received.	f the CERTIFIED copies	s of the priority documents	have been		
☐ received in Application No.☐ received in this national statement					
*Certified copies not received	•			•	
Attachment(e)					

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

✓ Notice of Reference(s) Cited, PTO-892

✓ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).

Part of Paper No. 9

☐ Interview Summary, PTO-413

☐ Other__

Office Action Summary

☐ Notice of Informal Patent Application, PTO-152

(703) 308-4850

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OFFICE ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121: 1.

Claims 1-17 and 24-27, drawn to a method and apparatus for optical analysis of a I.

sample, classified in class 436, subclass 172.

Claims 18-23, drawn to methods for optimizing the characteristic optical response II. signature of a sensor array having subpopulations of sensor elements, classified in class 250, subclass 459.1.

The inventions are distinct, each from the other because of the following reasons: 2.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the method and apparatus of the invention of Group I do not recite the particular operation of summation claimed in the invention of Group II for optimizing a signal corresponding to a characteristic optical response signature of a sensor array. The subcombination has separate utility such as for optimizing characteristics of optically responsive arrays per se, or for analysis without chemical indicators or reactions.

- Because these inventions are distinct for the reasons given above and have acquired a 3. separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- During a telephone conversation with R. Dennis Creehan (Reg. No. 39,950) on March 25, 1999, a provisional election was made without traverse to prosecute the invention of Group II, claims 18-23. Affirmation of this election must be made by applicant in replying to this Office

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action. Claims 1-17 and 24-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 6. Claims 1-17 and 24-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 6.
- 7. Applicant's election without traverse of the invention of Group II, claims 18-23, in Paper No. 6 is acknowledged.
- 8. Claims 28-38 are the same patentable invention as claims 18-23.
- 9. An action on the merits follows.

Information Disclosure Statement(s)

- 10. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
- 11. Any information disclosure statement filed January 19, 1999 has been misplaced by the Office. Resubmission and appropriate evidence of the content of the filing will allow the Examiner to complete the Form PTO-1449 on the basis of 37 CFR 1.97(b)(3).

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Oath/Declaration

12. The United States Postal Service standardizes the post office address for inventor WALT this way:

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4 CANDLEWICK CLOSE LEXINGTON MA 02421-4336

It is possible that the ZIP Code has been changed in the meantime.

Drawing(s)

- 13. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
- 14. Applicant is cautioned that Figs. 3, 11, and 12 raise a difficulty in that the separation of the elements into Figs. 3A, 3B, 11A, 11B, 12A, 12B is not apparent.

Specification

15. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Note the use of "is... disclosed...."

16. The disclosure is objected to because of the following informalities: page 4, line 20, the spelling of the fourth word; page 28, line 6, all references to the figures must include letter designations, *i.e.*, there is no "Fig. 3"; page 30, line 2, the capitalization of the unit name "watt" is improper; page 40, line 15 and elsewhere, the use of the letter "u" as a substitute for the prefix

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symbol -- μ -- is improper; page 43, line 8, the spelling of the first word; page 45, lines 5 and 10, all references to the figures must include letter designations, *i.e.*, there is no "Fig. 11" or "Fig. 12".

Appropriate correction is required.

- 17. Applicant is inconsistent on the capitalization of the symbol for the unit "liter".
- 18. Section 608.01 of the MPEP states in part:

In order to minimize the necessity in the future for converting dimensions... to the metric system of measurements when using printed patents... all patent applicants should use the metric (S.I.) units followed by the equivalent English units when describing their inventions....

The Assistant Secretary and Commissioner of Patents and Trademark strongly reiterated and emphasized strong encouragement for patent applicants to use the metric system in patent applications in a message appearing at 1135 O.G. 55 dated February 18, 1992. At some future time, the PTO will consider making it a requirement.

Note the use of the micron (which has not been a unit of the SI since 1967) and the language-dependent constructions "ppm" and "rpm". Note the use on page 44, at least, of the phrase"% by weight" (the percent sign is considered to represent the number 0.01 and cannot take a label). The Examiner is unable to require the use of SI units.

19. The use of the trademark NAFION has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

No generic language has been supplied for this solid superacid catalyst.

20. The use of the trademark NILE RED has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The trade name has not always been capitalized. See, for example, page 41, line 1.

21. The use of the trademark TWEEN 20 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

No generic language has been supplied for this detergent.

Claim(s) — Objection(s)

22. Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 28 requires that the method is for *reducing* the signal-to-noise ratio, not increasing it.

Claim(s)—Rejection(s)/35 U.S.C. 112

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24. Claims 28-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The

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specification does not enable a method to *reduce* the signal-to-noise ratio as recited by claim 1. As is apparent from the discussion relating to Fig. 14, the method comprising the steps of measurement and summation are to increase the signal-to-noise ratio.

Claim(s) - Rejection(s)/35 U.S.C. 103

- 25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).
- 27. Claims 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. (US005866331A).

With respect to independent claim 28, as best understood in view of the specification,
Singer et al. discloses a method for addressing the characteristic optical response signature
(fluorescence) of a sensor array having subpopulations of sensor elements (probes) comprising the
steps of measuring the optical response signature of at least two of the sensor elements of at least
one of the subpopulations (col. 7, lines 1-2) and summing the optical response signatures (col. 7,

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lines 5-7). "All pixels" represents at least two of the sensor elements of at least one of the subpopulations. In the context of a method capable of detecting and locating a single target-bound probe, it would have been obvious to one of ordinary skill in the art that the method of Singer et al. improved the signal-to-noise ratio in the characteristic optical response signature.

With respect to dependent claim 29, the baseline of at least one optical response signature is adjusted in the method of Singer et al. (col. 7, lines 4-5).

With respect to dependent claim 30, the improvement in the signal-to-noise ratio in the method of Singer et al. is a choice within the ordinary skill in the art in view of the desired performance.

With respect to dependent claim 31, a reduction in the analyte detection limit in the method of Singer et al. is a choice within the ordinary skill in the art in view of the desired performance.

With respect to dependent claim 32, the sensor array in the method of Singer et al. comprises a population of beads dispersed on a substrate (col. 13, lines 58-60).

With respect to dependent claim 33, although the substrate in the method of Singer et al. is the microscope slide or cover slip, the provision of a fiber optic bundle would have been within the ordinary skill in the art in view of the flexibility afforded in positioning the sensor array.

With respect to dependent claim 34, the method of Singer et al. further comprises the step of locating each sensor element (abstract, line 6) in view of the imaging techniques and CCD camera.

With respect to dependent claim 35, the sensor elements in the method of Singer et al. comprise chemical functional groups (col. 10, lines 52-57).

With respect to dependent claim 36, the sensor elements in the method of Singer et al. comprise oligonucleotides (col. 4, lines 54-57).

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With respect to independent claim 37, as best understood in view of the specification,
Singer et al. discloses a method for addressing the characteristic optical response signature
(fluorescence) of a sensor array having subpopulations of sensor elements (probes) comprising the
steps of measuring the optical response signature of at least two of the sensor elements of at least
one of the subpopulations (col. 7, lines 1-2) and summing the optical response signatures (col. 7,
lines 5-7). "All pixels" represents at least two of the sensor elements of at least one of the
subpopulations. In the context of a method capable of detecting and locating a single target-bound
probe, it would have been obvious to one of ordinary skill in the art that the method of Singer et al.
amplified the characteristic optical response signature.

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With respect to dependent claim 38, the baseline of at least one optical response signature is adjusted in the method of Singer et al. (col. 7, lines 4-5).

Comment on Submission(s)

28. The amendment filed March 29, 1999 has been entered.

Conclusion

- 29. Papers related to Technology Center 2800 applications **only** may be submitted to Technology Center 2800 by facsimile transmission. Any transmission not to be considered an official response must be clearly marked "DRAFT". The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 34-35 (November 15, 1988). The Fax number for Group Art Unit 2878 is (703) 308-7722 or (703) 308-7724.
- 30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Hannaher whose telephone number is (703) 308-4850.

It is a PTO-wide customer service standard that if the PTO employee being called is not available, that employee will return your telephone call by the next business day, or provide an alternate point of contact.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 2800 receptionist whose telephone number is (703) 308-0956.

Constantine Hannaher Primary Examiner

ch: 1999-08-09